PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
227-03895		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL2004/000034	13.01.2004	13.01.2003
International Patent Classification (IPC) or both national classification and IPC		
A61B5/00		
Applicant		
GLUCON INC. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
11.08.2004	20.09.2004
Name and mailing address of the international preliminary examining authority:	Authorized Officer
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IL2004/000034

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-30 as originally filed

Claims, Numbers

1-61 as originally filed

Drawings, Sheets

1-5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   - ☐ the description, pages:
   - ☐ the claims, Nos.:
   - ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	3-52, 54-56, 61
	No:	Claims	1, 2, 53,57-60
Inventive step (IS)	Yes:	Claims	4-52, 54-56
	No:	Claims	3, 61
Industrial applicability (IA)	Yes:	Claims	1-61
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:

D1: WO 91/18548 A (CLIFT VAUGHAN) 12 December 1991 (1991-12-12)
D2: WO 01/66005 A (DISETRONIC LICENSING AG ;REIHL BRUNO (CH); HAUETER ULRICH (CH)) 13 September 2001 (2001-09-13)

2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1 and 59 is not new in the sense of Article 33(2) PCT.

2.1 Document D1 discloses (the references in parentheses applying to this document):

A method of assaying an analyte in a body part comprising:
illuminating the body part with at least one pulse of light at each of first and second wavelengths (p. 4, lines 14-16) that stimulates photoacoustic waves (p. 7, lines 25-27) in first, target, region and a second, reference, region of the body part (p. 7, lines 20-23; "...pair of chambers..." which can be defined as target and reference region), wherein the reference region interfaces with the target region (Fig. 9; transducer 14 is between the chambers 15 and 15a and therefore the two regions are interfaced) and has at least one known optoacoustic property (p. 4, lines 8 - p. 5. line 3; the experimentally derived constants are based on known optoacoustic properties of the "interfering components" (water etc.), which properties are well known in the art) and wherein light at the first wavelength is absorbed and/ or scattered by the analyte (p. 4, lines 8-20);
sensing pressure in the photoacoustic waves from the target and reference regions stimulated by the light at the first and second wavelengths (p. 7, lines 20-27); and using the sensed pressure and the at least one known optoacoustic property to assay the analyte in the target region (p. 6, lines 12-20 and p. 4, lines 8-28; "...the result of the measuring is corrected by taking into account the

absorption caused by the interfering components..." (water, protein and fat etc.), which properties are well known in the art).

2.2 It is indicated, that D1 does not explicitly define the expression "stimulating photoacoustic waves" as set out in present claim 1. However, D1 teaches in particular on page 11 line 29-page 12, line 3, that the adsorbed light pulse (optical energy) causes a rapid increase of the local tissue temperature (thermal energy) which subsequently results in a pressure wave (acoustic energy). This physical effect, which is known in the art as a "photoacoustic effect", always primarily transfers optical energy into thermal energy (light is adsorbed and heats up the tissue), the medium expands thus leading to the acoustic signal. From the physical point of view, it is not possible to transfer optical energy "directly" into an acoustic pressure wave. Therefore, the signals detected by the pressure transducers 14 in D1 are indeed "photoacousic waves".

The subject-matter of **claim 1** is therefore **not novel (Article 33(2) PCT)** .

3 **Claim 59** has been drafted as a further independent claim, it defines effectively the same subject-matter as claim 1 and differs from this claim only with regard to the definition of the subject-matter for which protection is sought in respect of the terminology used for the features of that subject-matter. The same reasoning applies, mutatis mutandis, to the subject-matter of claim 59 as stated above, which therefore is also considered **not novel** (Article 33(2) PCT).

4 Dependent **claims 2** and **60**, which define the same subject-matter, are also anticipated by D1 and therefore **not novel** (Article 33(2) PCT) (see Fig. 8 and p.11, lines 16-17; "skin").

5 The subject-matter of dependent **claims 3** and **61**, which define also the same subject-matter, does **not involve an inventive step in the sense of Article 33(3)** PCT, because D2, which discloses a similar method for assaying substances in body fluid, discloses the use of an artificial implant located in the body (p. 10, line 23-25 "Reflektor") for the same result to be achieved, namely to use known optical properties in a reference region under the tissue to determine the concentration of an analyte. It would be obvious to the person skilled in the art to include this method step in the method according to D1.

5.1 Dependent **claims 53, 57, 58** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see the corresponding passages cited in the search report.

6 The combination of the features of dependent **claims 4-52, 54-56** is neither known from, nor rendered obvious by, the available prior art because no document teaches the use of an artificial implant in a method according to claim 3 to determine a concentration of an analyte with a function dependent on known properties (of the artificial implant) and having dependence on the pressure only through ratios of pressures. The problem to solved by this method is to increase the accuracy of the determined absorption coefficient and concentration of the analyte at a given location in a tissue region.